Substitu	ite for form 1449A/P	то			Complete if Known	
		. •		Application Number	Unassigned	
INF	ORMATION	V DI	SCLOSURE	Filing Date	Herewith	
STATEMENT BY APPLICANT			PPLICANT	First Named Inventor	Karimisetty, Srikanth	
				Art Unit	Unassigned	
	(use as many sh	eets a	s necessary)	Examiner Name	Unassigned	
Sheet	1	of	2	Attorney Docket Number	021756-002000US	

			U.S. PATENT DO	CUMENTS+	
		Document Number			
Examiner Initials*	Cite No. ¹	'Number Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
/NP/	AA	US-6,456,955 B1	09-24-2002	Andrews et al.	
	AB	US-6,584,459 B1	06-24-2003	Chang et al.	
	AC	US-2002-0023083 A1	02-21-2002	Durkalski	
	AD	. US-2002-0107652 A1	08-08-2002	Andrews et al.	
	AE	US-2002-0143726 A1	10-03-2002	Planalp et al.	
	AF	US-2003-0069795 A1	04-10-2003	Boyd et al.	
V	AG	US-2003-0069894 A1	04-10-2003	Cotter et al.	
/NP/	AH	US-2003-0088776 A1	05-08-2003	· Lin et al.	
	L	ļ			
	L.,	<u> </u>		,	

	FOREIGN PATENT DOCUMENTS							
Examiner	Cite	Foreign Patent Document				Name of Patentee or	Pages, Columns, Lines,	
Initials*	No.¹	Country Code ³	Number ⁴	Kind Code ⁶ (# known)	Publication Date MM-DD-YYYY	Applicant of Cited Document	Where Relevant Passages or Relevant Figures Appear	Ţ ⁶
		ļ						
								
				*				
		1			·			
		 						
	L				L		1	

Examiner		Date	00/07/2007
Signature	/Nirav Patel/	Considered	06/07/2007

Substitute	for form 1449B/	/PTO		C mpl te if Known		
INEO	DRAATIO	N DIC	CLOCUEE	Application Number	Unassigned	
			CLOSURE	Filing Date	Herewith .	
SIAI	EMENT	BY A	PPLICANT	First Named Inventor	Karimisetty, Srikanth	
				Art Unit	Unassigned	
(use as many sheets as necessary)				Examiner Name	Unassigned	
Sheet	2	of	2	Attorney Docket Number	021756-002000US	

		NON PATENT LITERATURE DOCUMENTS				
Examiner Initials *						
/NP/	Al	*FDA 21 CFR Part 11,* Document Resources, http://www.documentresources.com/document/21cfrpart11.html, pp. 1-2, printed June 23, 2003.				
/NP/	W	"The Role of Technology Solutions in the Pharmaceutical and Biotechnology Industries' Search for 21 CFR Part 11 Compliance," Life Science CIO Forum, www.lifesciencesCIOforum.com, pp. 1-7 (2002).				
/NP/	AK	*21CFR Part 11 Opportunity or Challenge? With an Analysis of Oracle's OPM,* Life Science CIO Forum, www.lifesciencesClOforum.com, pp. 1-14 (2002).				
		3				
			1			
						

	y' ' ' ' ' ' ' ' ' ' ' ' ' ' ' ' ' ' ' 		
Examiner Signature	/Nirav Patel/	Date Considered	06/07/2007

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached.